

CLAIMS

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B1/71.

1. A method of contraception comprising the steps of sequentially-administering to a female of child bearing age:

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(1) for about 4 to about 7 days, a composition I containing about 0.5-1.5 mg norethindrone acetate and about 10-50 mcg ethinyl estradiol,

(2) for about 5 to about 8 days, a composition II containing about 0.5-1.5 mg norethindrone acetate and about 10-50 mcg ethinyl estradiol, and

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(3) for about 7 to about 12 days, a composition III containing 0.5-1.5 mg norethindrone acetate and about 10-50 mcg ethinyl estradiol, wherein the amount of ethinyl estradiol is increased stepwise over the three compositions.

2. The method of Claim 1 which comprises the additional step of administering, for about 7 days, a composition ^{IV} containing ferrous fumarate.

3. The method of Claim 1 wherein composition I contains about 0.5-1.5 mg norethindrone acetate and about 10-30 mcg ethinyl estradiol; composition II contains 0.5-1.5 mg norethindrone acetate and 20-40 mcg ethinyl estradiol; and composition III contains 0.5-1.5 mg norethindrone acetate and about 30-50 mcg ethinyl estradiol.

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4. The method of Claim 1 wherein composition I is administered for about 5 days and contains about 1.0 mg norethindrone acetate and about 20 mcg ethinyl estradiol; composition II is administered for about 7 days and contains about 1.0 mg norethindrone acetate and about 30 mcg ethinyl estradiol; and composition III is administered for about 9 days and

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contains about 1.0 mg norethindrone acetate and about 40 mcg ethinyl estradiol.

Claim 5 >

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Sub B2

5. The method of Claim 4 wherein at least one composition is administered in combination with a suitable carrier.

6. The method of Claim 1 wherein composition I is administered for about 5 days and contains about 1.0 mg norethindrone acetate and about 20 mcg ethinyl estradiol; composition II is administered for about 7 days and contains about 1.5 mg norethindrone acetate and about 30 mcg ethinyl estradiol; and composition III is administered for about 9 days and contains about 1.0 mg norethindrone acetate and about 50 mcg ethinyl estradiol.

Claim 7 >

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Sub B3

7. The method of Claim 6 wherein at least one composition is administered in combination with a suitable carrier.

8. The method of Claim 1 wherein composition I is administered for about 5 days and contains about 1.0 mg norethindrone acetate and about 20 mcg ethinyl estradiol; composition II is administered for about 7 days and contains about 1.0 mg norethindrone acetate and about 30 mcg ethinyl estradiol; and composition III is administered for about 9 days and contains about 1.0 mg norethindrone acetate and about 35 mcg ethinyl estradiol.

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Sub B4

9. The method of Claim 8 wherein at least one composition is administered in combination with a suitable carrier.

10. A multiphase combination and contraceptive kit comprising a package containing daily dosages of:
- 5 (1) a Phase I composition containing about 0.5-1.5 mg norethindrone acetate and about 10-50 mcg ethinyl estradiol;
- (2) a Phase II composition containing about 0.5-1.5 mg norethindrone acetate and about 10-50 mcg ethinyl estradiol; and
- 10 (3) a Phase III composition containing about 0.5-1.5 mg norethindrone acetate and about 10-50 mcg ethinyl estradiol, wherein the amount of ethinyl estradiol is increased stepwise over the three compositions.
11. The kit of Claim 10 which additionally comprises a Phase IV composition containing ferrous fumarate.
12. The kit of Claim 11 wherein the composition for Phase IV contains about 75 mg ferrous fumarate.
13. A multiphase combination and contraceptive kit comprising a package containing:
- 5 (1) about 4 to 7 dosages of a Phase I composition containing about 0.5-1.5 mg norethindrone acetate and about 10-30 mcg ethinyl estradiol;
- (2) about 5 to 8 dosages of a Phase II composition containing about 0.5-1.5 mg norethindrone acetate and about 20-40 mcg ethinyl estradiol, and
- 10 (3) about 7 to 12 dosages of a Phase III composition containing about 0.5-1.5 mg norethindrone acetate and about 30-50 mcg ethinyl estradiol, wherein the amount of ethinyl estradiol is increased stepwise over the three compositions.

14. The kit of Claim 13 which additionally comprises about 9 dosages of a Phase IV composition containing ferrous fumarate.
15. The kit of Claim 14 wherein the composition for Phase IV contains about 75 mg ferrous fumarate.
16. The kit of Claim 13 wherein the Phase I composition contains about 1.0 mg norethindrone acetate and about 20 mcg ethinyl estradiol; the Phase II composition contains about 1.0 mg
5 norethindrone acetate and about 30 mcg ethinyl estradiol; and the Phase III composition contains about 1.0 mg norethindrone acetate and about 40 mcg ethinyl estradiol.
17. The kit of Claim 16 containing about 5 dosages of the Phase I composition, about 7 dosages of the Phase II composition, and about 9 dosages of the Phase III composition.
18. The kit of Claim 13 wherein the Phase I composition contains about 1.0 mg norethindrone acetate and about 20 mcg ethinyl estradiol; Phase II composition contains about 1.5 mg
5 norethindrone acetate and about 30 mcg ethinyl estradiol; and the Phase III composition contains about 1.0 mg norethindrone acetate and about 50 mcg ethinyl estradiol.
19. The kit of Claim 18 containing about 5 dosages of the Phase I composition, about 7 dosages of the Phase II composition, and about 9 dosages of the Phase III composition.

20. The kit of Claim 13 wherein the Phase I composition contains about 1.0 mg norethindrone acetate and about 20 mcg ethinyl estradiol; the Phase II composition contains about 1.0 mg norethindrone acetate and about 30 mcg ethinyl estradiol; and the Phase III composition contains about 1.0 mg norethindrone acetate and about 35 mcg ethinyl estradiol.
21. The kit of Claim 20 containing about 5 dosages of the Phase I composition, about 7 dosages of the Phase II composition, and about 9 dosages of the Phase III composition.